DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Transonic Systems Incorporated
Ms. Leah Van De Water
Senior Regulatory Affairs Manager
34 Dutch Mill Road
Ithaca, New York 14850

July 23, 2015

Re: K140740
Trade/Device Name: Transonic Tissue Perfusion Monitors
Regulation Number: 21 CFR 870.2100
Regulation Name: Cardiovascular blood flowmeter
Regulatory Class: Class II
Product Code: DPW
Dated: June 8, 2015
Received: June 9, 2015

Dear Mr. Klementowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140740

Device Name
Transonic Tissue Perfusion Monitors
Model numbers: BLF22 and BLF22A.

Indications for Use *(Describe)*
Transonic Systems' BLF22 and BLF22A tissue perfusion monitors are intended for use in the measurement of microvascular perfusion.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

Summary of Safety & Effectiveness

Submitter's Name & Address: Transonic Systems, Inc.
34 Dutch Mill Road
Ithaca, NY 14850

Contact Person & Telephone: Leah Van De Water
607-257-5300

Date Summary Prepared: March 24, 2014 (Revised July 17, 2015)

Device Name:

Proprietary Name – Transonic Tissue Perfusion Monitor
Common/Usual Name – Laser Doppler Meter
Classification Name – Cardiovascular Blood Flowmeter (21 CFR 870.2100)
Product Code: DPW
Regulatory Class: II

Predicate Device: K903633 ALF21 Laser Flow Meter

Device Description:

The BLF22 (single-channel) Tissue Perfusion Monitor reports Flow, Mass or Velocity on its front panel digital display. Housed in a small metal case, the Monitor is equipped with a convenient multi-position handle/stand. It also features: rear panel analog outputs for Flow/Mass/Velocity in 0 - 10 Volts DC; and a USB computer interface.

The BLF22A (single-channel + Indicator Tone) Tissue Perfusion Monitor incorporates all the functionality of the BLF22, plus adjustable Low Flow Indicator Tone circuitry. This will sound an audio signal when tissue perfusion flow drops below a preset level.

Models:
Transonic Systems Laser Doppler BLF22 Series monitors consist of the following model numbers: BLF22 and BLF22A.

Indications for Use (Prescription Device):
Transonic Systems' BLF22 and BLF22A tissue perfusion monitors are intended for use in the measurement of microvascular perfusion.

Substantial Equivalence:
The Transonic BLF22 and BLF22A Monitors are similar in materials, form, and operating principle to the ALF21 Laser Flowmeter in K903633. The BLF22 and BLF22A monitors have

the same principle of operation and electronics design. The case and circuit has been updated to utilize alarm electronics, clinical power supply, and poser entry module inside the case.

Performance Testing:
Bench studies demonstrated the functional requirement specifications of the BLF22 and BLF22A including flow values and messages to user.

Electrical safety testing was conducted and the BLF22/ BLF22A comply with IEC 60601-1.

The product is tested and must meet all required release specifications before distribution. Testing is completed for the tissue perfusion probe/monitor combination demonstrating the volume flow is measured within the specified full range and accuracy.

Animal and clinical testing was not required to support substantial equivalence.

The successful testing demonstrates the safety and effectiveness of the BLF22 and BLF22A Tissue Perfusion Monitors when used for the defined indications for use.

Conclusion:
The sponsor believes that the BLF22 and BLF22A tissue perfusion monitoring systems utilize similar technology as the predicate K903633 device. The sponsor has provided technical performance specifications and testing data. This information demonstrates that the devices do not raise new types of questions regarding safety or effectiveness when compared to the K903633 device and when used for the indications for use provided above. The sponsor thus concludes that the BLF22 and BLF22A devices are substantially equivalent to the predicate K903633 ALF21 device.